DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 2/14/11. Claim(s) 1-40 are pending. Claim(s) 21 and 32 have been amended. Claim(s) 1-20, 25-27, 30-31, 36-38 have been withdrawn. Claim(s) 21-24, 28-29, 32-35, 39-40 are examined herein.

In view of the claim amendments filed on 2/14/2011 and the Examiner's Amendment below, all rejections of the previous Office Action are hereby withdrawn.

Upon further consideration, the restriction requirement filed on 1/16/2007 is hereby withdrawn.

The terminal disclaimer filed on 10/27/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent Application 11/821,221 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. John G. Babish on 5/5/2011.

The application has been amended as follows:

Please cancel claims 1-20, 22-31, 33-40.

In claim 21, please delete the comma after "treating".

In claim 21, after "consisting of administering to said subject", please insert "a composition consisting of".

In claim 21, after "non-active ingredients", please delete "including flavors and coloring agents, emulsifiers, preservatives and a pharmaceutically acceptable carrier in concert with anti-retroviral therapies" and insert "selected from the group consisting of flavors, coloring agents, emulsifiers, preservatives and a pharmaceutically acceptable carrier".

In claim 32, after "consisting of administering to said subject", please insert "a composition consisting of".

In claim 32, after "non-active ingredients", please delete "including flavors and coloring agents, emulsifiers, preservatives and a pharmaceutically acceptable carrier in concert with anti-retroviral therapies" and insert "selected from the group consisting of flavors, coloring agents, emulsifiers, preservatives and a pharmaceutically acceptable carrier".

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The closest prior art is McCleary (US Patent Application 2002/0132219 A1) and Medford et al. (US Patent 5,750,351) in view of Applicant's admission of the prior art.

Applicant present evidence that clinically N-acetyl cysteine (NAC) functions as a pro-oxidant relative to its ability to inhibit the oxidation of LDL or reduced serum lipids, therefore not obvious to use NAC as an antioxidant. Specifically, the clinical findings of Kleinveld in 1992 and McComsey et al. in 2003 make it clear that NAC does not function as an antioxidant for the purpose of reducing ox-LDL or serum lipids.

Moreover, it is not obvious to substitute the antioxidant, Coenzyme Q10, for NAC because Coenzyme Q10 was not used for its antioxidant properties, but for facilitating respiratory chain function and hence augments the process of reverse electron transport. The McCleary reference uses Coenzyme Q10 in combination with additional active agents, which have been precluded by the amended claims, which now recite the closed transitional phrase "consisting of".

With regards to conjugated linoleic acid (CLA), at the time of the claimed invention, seven of eight published clinical studies indicated a lack of effect of CLA on lowering blood lipids. The authors of this review concluded, "the evidence from human, short term studies suggest that CLA supplementation does not reduce body fat or increase fat-free mass." Further reviews of CLA research in patients with metabolic syndrome and diabetes confirm adverse, clinical effects of CLA in a variety of human

conditions including diabetes. Applicant has presented a detailed mechanism of action to show that NF-kB is not linked to hyperlipidemia.

Finally, Applicant has presented unexpected results in the Babish Declaration 4 under 37 CFR 1.132 filed 2/14/2011. Since the prior art concerning the inoperability of CLA or NAC for decreasing blood lipids or increasing subcutaneous fat clinically describes a situation in which neither Factor A or Factor B functions successfully. The Babish Declaration 4 shows that the combination of two nonfunctioning factors results in a successful result is an example of the unexpected advantage as evidenced in Figure 1 and 2.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1627

YSC